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Docket No.: 19240.594 US1  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrew R. Marks Confirmation No.: 6915

Application No.: 10/608723 Art Unit: 1646

Filed: June 26, 2003 Examiner: R. Li

Title: METHODS FOR TREATING AND PREVENTING CARDIAC  
ARRHYTHMIA

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

Dear Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants bring to the attention of the Examiner the documents listed on the attached Form PTO SB-08. Copies of the documents listed are not submitted herewith. These documents were previously cited by or submitted to the United States Patent and Trademark Office in U.S. Patent Application No. 10/288,606, filed November 5, 2002 and is relied upon in this application for an earlier filing date under 35 U.S.C. 120.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114. No certification or fee is believed to be due. If, however, a fee is due, please charge our Deposit Account No. 08-0219. Applicants request that the Examiner initial and return a copy of the enclosed Form PTO SB-08 with the next communication.

Respectfully submitted,

Dated: August 3, 2006

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PTO/SB/08a/b (07-05)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/608723-Conf. #6915	
			Filing Date	June 26, 2003	
			First Named Inventor	Andrew R. Marks	
			Art Unit	1646	
Sheet	1	of	10	Examiner Name	R. Li
				Attorney Docket Number	19240.594 US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA**	US-10/763,498	01-22-2004	Marks et al.	
	AB**	US-20030134331-A1	07-17-2003	Andrew Marks	
	AC**	US-20040173802	09-09-2004	Yukimoto	
	AD**	US-20040048780-A1	03-11-2004	Andrew Marks	
	AE**	US-20040229781-A1	11-18-2004	Marks et al.	
	AF**	US-20050215540-A1	09-29-2005	Marks et al.	
	AG**	US-4,990,707	02-05-1991	Mais et al.	
	AH**	US-5,221,681	06-22-1993	Kabbe et al.	
	AI**	US-5,416,066	05-16-1995	Kaneko et al.	
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	AK**	US-5,580,866	12-03-1996	Housley et al.	
	AL**	US-5,723,458	03-03-1998	Brieady et al.	
	AM**	US-5,859,240	01-12-1999	Brieady	
	AN**	US-5,910,494	06-08-1999	Brieady	
	AO**	US-6,489,125	12-03-2002	Marks et al.	
	AP**	US-6,506,745	01-14-2003	Aisaka et al.	
	AQ**	US-20040224368-A1	11-11-2004	Marks et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA**	WO-99/26921	06-03-1999	Merck & Co., Inc.		
	BB**	JP-10045706	02-17-1998	Sumitomo Seika Chem Co Ltd.		
	BC**	WO-02/051838	07-04-2002	Actelion Pharmaceuticals Ltd.		
	BD**	JP-3093419	04-18-1991	Mitsubishi Cable Ind Ltd.		
	BE**	WO-01/00185	01-04-2001	Knoll Aktiengesellschaft		
	BF**	JP-11199574	07-27-1999	Ube Ind Ltd.		
	BG**	WO-97/03986	02-06-1997	Yoshitomi Pharmaceutical Industries, Ltd.		
	BH**	JP-05/271208	10-19-1993	Kirin Brewery Co Ltd.		
	BI**	WO-99/32115	07-01-1999	The University of the West Indies		
	BJ**	WO-02/053548	07-11-2002	Banyu Pharmaceutical Co. Ltd.		
	BK**	WO-94/29286	12-22-1994	G.D. Searle & Co.		
	BL**	WO-03/034980	05-01-2003	New River Pharmaceuticals Inc.		
	BM**	WO-04/022057	03-18-2004	Aventis Pharma Deutschland GMBH		
	BN**	WO-02/051232	07-04-2002	Actelion Pharmaceuticals Ltd.		
	BO**	WO-92/12148	07-23-1992	KANEKO et al.		
	BP**	WO-98/05657	02-12-1998	Knoll Aktiengesellschaft		
	BQ**	JP-4230681	08-19-1992	Kirin Brewery Co. Ltd.		

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \*\* CITE NO.: Those document(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA**	Ahern et al., "Intramembrane Charge Movements and Excitation-Contraction Coupling Expressed by Two-Domain Fragments of the Ca <sup>2+</sup> Channel." Proc Natl Acad Sci USA, Vol. 98, No. 12, pp. 6935-6940. (2001).	
	CB**	Ahern et al., "Subconductance States in Single-Channel Activity of Skeletal Muscle Ryanodine Receptors After Removal of FKBP12." Biophys J, Vol. 72, pp. 146-162. (1997).	
	CC**	Ahmed, G.U. et al., "Changes in Ca(2+) Cycling Proteins Underlie Cardiac Action Potential Prolongation in a Pressure-Overloaded Guinea Pig Model with Cardiac Hypertrophy and Failure." Circ. Res., Vol. 86, No. 5, pp. 558-570. (2000).	
	CD**	Alvarez et al. "Late Post Myocardial Infarction Induces a Tetrodotoxin-Resistant Na <sup>+</sup> Current in Rat Cardiomyocytes." J. Mol. Cell Cardiol, Vol. 32, pp. 1169-1179. (2000).	
	CE**	Antos et al. "Dilated Cardiomyopathy and Sudden Death Resulting from Constitutive Activation of Protein Kinase A." Circ. Res., Vol. 89, pp. 997-1004. (2001).	
	CF**	Barbone et al. "Comparison of Right and Left Ventricular Responses to Left Ventricular Assist Device Support in Patients with Severe Heart Failure: A Primary Role of Mechanical Unloading Underlying Reverse Remodeling." Circulation, Vol. 104, pp. 670-675. (2001).	
	CG**	Basso, C. et al., "Arrhythmogenic Right Ventricular Cardiomyopathy Causing Sudden Cardiac Death in Boxer Dogs: A New Animal Model of Human Disease." Circulation, Vol. 109, No. 9, pp. 1180-1185. (2004).	
	CH**	Bennett et al. "The Pattern of Onset and Spontaneous Cessation of Atrial Fibrillation in Man." Circulation, Vol. 41, pp. 981-988. (1970).	
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	CK**	Bristow et al., "Carvedilol Produces Dose-Related Improvements in left Ventricular Function and Survival in Subjects with Chronic Heart Failure." Circulation, Vol. 94, pp. 2807-2816. (1996).	
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	CN**	Catsoulacos, "Synthesis of Substituted Dihydrobenzothiazepines and Related Compounds." J Heterocyclic Chemistry, Vol. 7, No. 2: pp. 409-411. (1970).	
	CO**	Cerrone, M. et al., "Bidirectional Ventricular Tachycardia and Fibrillation Elicited in a Knock-in Mouse Model Carrier of a Mutation in the Cardiac Ryanodine Receptor." Circ. Res., Vol. 96,	
Examiner Signature			Date Considered

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				Examiner Name	R. Li
Sheet	3	of	10	Attorney Docket Number	19240.594 US1

		No. 10, e77-82. (2005).	
	CP**	Chen, Ye-Guang et al., "Mechanism of TGF $\beta$ Receptor Inhibition by FKBP12." The EMBO Journal, Vol. 16, No. 13, pp. 3866-3876. (1997).	
	CQ**	Cheng, H. et al., "Amplitude Distribution of Calcium Sparks in Confocal Images: Theory and Studies with an Automatic Detection Method." Biophys J., Vol. 76, pp. 606-617. (1999).	
	CR**	Chidsey et al. "Augmentation of Plasma Nor-epinephrine Response to Exercise in Patients with Congestive Heart Failure." N. Engl. J. Med. Vol. 267, No. 13, pp. 650-654. (1962).	
	CS**	Chugh et al. "Epidemiology and Natural History of Atrial Fibrillation: Clinical Implications." J. Am. Coll. Cardiol., Vol. 37, No.2, pp. 371-378. (2001).	
	CT**	Cranefield, P.F. "Action Potentials, Afterpotentials and Arrhythmias." Circ. Res., Vol. 41, No. 4, pp. 415-423. (1977).	
	CU**	Daoud et al. "Effect of Verapamil and Procainamide on Atrial Fibrillation-Induced Electrical Remodeling in Humans." Circulation, Vol. 96, pp. 1542-1550. (1997).	
	CV**	Dietz et al., "Epinephrine Regulation of Skeletal Muscle Glycogen Metabolism :Studies Utilizing the Perfused Rat Hindlimb Preparation." J. Biol. Chem., Vol. 255, No. 6, pp. 2301-2307. (1980).	
	CW**	Drexler et al. "Contrasting Peripheral Short-Term and Long-Term Effects of Coverting Enzyme Inhibition in Patients with Congestive Heart Failure. A Double-Blind, Placebo-Controlled Trial." Circulation, Vol. 79, pp. 491-502. (1989).	
	CX**	Dun et al. "Chronic Atrial Fibrillation Does Not Further Decrease Outward Currents. It Increases Them." Am. J. Physiol. Heart Circ. Physiol., Vol. 285, pp. H1378-1384. (2003).	
	CY**	Eichhorn et al. "Medical Therapy can Improve the Biological Properties of the Chronically Failing Heart. A New Era in the Treatment of Heart Failure." Circulation, Vol. 94, pp. 2285-2296. (1996).	
	CZ**	Elvan et al. "Pacing-induced Chronic Atrial Fibrillation Impairs Sinus Node Function in Dogs: Electrophysiological Remodeling." Circulation, Vol. 94, pp. 2953-2960. (1996).	
	CA1**	Falk, R.H. "Atrial Fibrillation." N. Engl. J. Med., Vol. 344, No. 14, pp. 1067-1078. (2001).	
	CB1**	Fodor et al. "New Convenient Synthesis of 1,4-benzothiazepines." Tetrahedron Letters, Vol. 36, No. 5, pp. 753-756. (1995).	
	CC1**	Fox, P.R., "Spontaneously Occurring Arrhythmogenic Right Ventricular Cardiomyopathy in the Domestic Cat: A New Animal Model Similar to the Human Disease." Circulation, Vol. 102, No. 15, pp. 1863-1870. (2000).	
	CD1**	Franzini-Armstrong et al., "Alternate Disposition of Tetrads in Peripheral Couplings of Skeletal Muscle." Journal of Muscle Research & Cell Motility." Vol. 16, pp. 319-324. (1995).	
	CE1**	Gaspo et al. "Functional Mechanisms Underlying Tachycardia-induced Sustained Atrial Fibrillation in a Chronic Dog Model." Circulation, Vol. 96, pp. 4027-4035. (1997).	
	CF1**	Goette et al. "Electrical Remodeling in Atrial Fibrillation: Time Course and Mechanisms." Circulation, Vol. 94, pp. 2968-2974. (1996).	
	CG1**	Gonzalez et al. "Involvement of Multiple Intracellular Release Channels in Calcium Sparks of Skeletal Muscle." Proc. Natl Acad Sci USA, Vol. 97, No. 8, pp. 4380-4385. (2000).	
	CH1**	Gullestad et al., "Effect of Metoprolol CR/XL on Exercise Tolerance in Chronic Heart Failure - a Substudy to the MERIT-HF Trial," Eur. J. Heart Fail, Vol. 3, pp. 463-468. (2001).	
	CI1**	Gwathmey et al. "Abnormal Intracellular Calcium Handling in Myocardium From Patients with End-Stage Heart Failure." Circ. Res., Vol. 61, pp. 70-76. (1987).	
	CJ1**	Hachida et al. "Significant Effect of 1,4-Benzothiazepine Derivative (K2) in Improving Myocardial Preservation." Transplantation Proceedings, Vol. 29, pp. 1346-1348. (1997).	
	CK1**	Hachida, et al., "Protective Effect of JTV519 (K201), a New 1, 4 - Benzothiazepine Derivative, on Prolonged Myocardia Preservation." Transplantation Proceedings, Vol. 31, pp. 996-1000. (1999).	
	CL1**	Hachida, M. et al. "Protective Effect of JTV-519, a new 1, 4-Benzothiazepine Derivative, on	

Examiner Signature		Date Considered	
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Sheet	4	of	10	Attorney Docket Number	19240.594 US1

		Prolonged Myocardial Preservation." J. Card. Surg., Vol. 14, pp. 187-193. (1999).	
CM1**	Hain, J. et al., "Phosphorylation Modulates the Function of the Calcium Release Channel of Sarcoplasmic Reticulum from Skeletal Muscle." Biophys. J. 67, pp. 1823-1833. (1994).		
CN1**	Hara et al., "Steady-state and nonsteady State Action Potentials in Fibrillating Canine Atrium: Abnormal Rate Adaption and Its Possible Mechanisms." Cardiovasc. Res., Vol. 42, pp. 455-469. (1999).		
CO1**	Harrington, D. et al. "Mechanisms of Exercise Intolerance in Congestive Heart Failure." Current Opinion in Cardiology, Vol. 12, No. 3, pp. 224-32. (1997).		
CP1**	Hasenfuss et al., "Treatment of Heart Failure Through Stabilization of the Cardiac Ryanodine Receptor." Circulation, Vol. 107, pp. 378-380. (2003).		
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CR1**	Inagaki et al. "The Cardioprotective Effects of a new 1,4-benzothiazepine Derivative, JTV 519, on ischemia/reperfusion-induced $Ca^{2+}$ Overload in Isolated Rat Hearts." Cardiovasc Drugs Ther., Vol. 14, pp. 489-495. (2000).		
CS1**	International Search Report and Written Opinion from PCT/US04/20474, August 30, 2005.		
CT1**	International Search Report and Written Opinion from PCT/US04/32550, October 18, 2005.		
CU1**	International Search Report and Written Opinion from PCT/US05/009495, March 14, 2006.		
CV1**	International Search Report and Written Opinion from PCT/US05/10055, October 27, 2005.		
CW1**	Isselbacher, Kurt J. et al. "Harrison's Principles of Internal Medicine." 13th Edition, Vol. 1, pp. 1022-1024. (1994).		
CX1**	Ito et al. "JTV-519, a Novel Cardioprotective Agent, Improves the Contractile Recovery after Ischaemia Reperfusion in Coronary Perfused Guinea Pig Ventricular Muscles." Br. J. Pharmacol., Vol. 130, No. 4, pp. 767-776. (2000).		
CY1**	Jiang et al., "Abnormal $Ca^{2+}$ Release, but Normal Ryanodine Receptors, in Canine and Human Heart Failure." Circulation Research, Vol. 91, pp. 1015-1022. (November 29, 2002).		
CZ1**	Kaftan, Edward et al. "Effects of Rapamycin on Ryanodine Receptor/ $Ca^{2+}$ -Release Channels from Cardiac Muscle." Circulation Research, Vol. 78, No. 6, pp. 990-997. (June 1996).		
CA2**	Kaneko et al., "Crystal Structure of Annexin V with Its Ligand K-201 as a Calcium Channel Activity Inhibitor." Journal of Molecular Biology, Vol. 274, pp. 16-20. (1997).		
CB2**	Kaneko et al., "Inhibition of Annexin V-dependent $Ca^{2+}$ Movement in Large Unilamellar Vesicles by K201, a New." Biochimica et Biophysica Acta, Vol. 1330, pp. 1-7. (1997).		
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CD2**	Kawabata et al. "A Novel Cardioprotective Agent, JTV-519, is abolished by Nitric Oxide Synthase Inhibitor on Myocardial Metabolism in Ischemia-Reperfused Rabbit Hearts." Hypertens Res., Vol. 25, pp. 303-309. (2002).		
CE2**	Kawabata et al. "Effect of a Novel Cardioprotective Agent, JTV-519, on Metabolism, Contraction and Relaxation in the Ischemia-Reperfused Rabbit Heart." Jpn Circ. J., Vol. 64, pp. 772-776. (2000).		
CF2**	Kiriyama et al. "Effects of JTV-519, a Novel Anti-Ischaemic Drug, on the Delayed Rectifier $K^{+}$ Current in Guinea-Pig Ventricular Myocytes." Naunyn Schmiedeberg's Arch Pharmacol. Vol. 361, No. 6, pp. 646-653. (2000).		
CG2**	Kirsch et al., "Spark and Ember-Like Elementary $Ca^{2+}$ Release Events in Skinned Fibre of Adult Mammalian Skeletal Muscle." J. Physiol., Vol. 537, No.2, pp. 379-389. (2001).		
CH2**	Kiryu, K. et al. "Pathologic and Electrocardiographic Findings in Sudden Cardiac Death in Racehorses." J. Vet. Med. Sci., Vol. 61, No. 8, pp. 921-928. (1999).		
CI2**	Kittleson, M.D. et al., "Familial Hypertrophic Cardiomyopathy in Maine Coon Cats: An Animal Model of Human Disease." Circulation, Vol. 99, No. 24, pp. 3172-3180. (1999).		

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Sheet	5	of	10	Attorney Docket Number	19240.594 US1

	CJ2**	Klein et al., "Voltage Dependence of the Pattern and Frequency of Discrete Ca <sup>2+</sup> Release Events After Brief Repriming in Frog Skeletal Muscle." Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 11061-11066. (1997).	
	CK2**	Kneller et al. "Remodeling of Ca <sup>2+</sup> - handling by Atrial Tachycardia: Evidence for a Role in Loss of Rate-Adaption." Cardiovasc. Res., Vol. 54., pp. 416-426. (2002).	
	CL2**	Kohn et al., "A New Cardioprotective Agent, JTV519, Improves Defective Channel Gating of Ryanodine Receptor in Heart Failure." Am J Physiol Heart Circ Physiol, Vol. 284, pp. H1035-H1042. (2003).	
	CM2**	Kukin, M.L. et al. "Prospective, Randomized Comparison of Effect of Long-Term Treatment with Metoprolol or Carvedilol on Symptoms, Exercise, Ejection Fraction, and Oxidative Stress in Heart Failure." Circulation, Vol. 99, pp. 2645-2651. (1999).	
	CN2**	Kumagai et al. "Antiarrhythmic Effects of JTV-519, a novel Cardioprotective Drug, on Atrial Fibrillation/Flutter in a Canine Sterile Pericarditis Model." J. Cardiovasc. Electrophysiol. Vol. 14, No. 8, pp. 880-884. (2003).	
	CO2**	Lacampagne, A. et al., "Modulation of the Frequency of Spontaneous Sarcoplasmic Reticulum Ca <sup>2+</sup> Release Events (Ca <sup>2+</sup> Sparks) by Myoplasmic (Mg <sup>2+</sup> ) Frog Skeletal Muscle." J. Gen. Physiol. 111, pp. 207-224. (1998).	
	CP2**	Lai, F.A., et al., "The Ryanodine Receptor-Ca <sup>2+</sup> Release Channel Complex of Skeletal Muscle Sarcoplasmic Reticulum. Evidence for a Cooperatively Coupled, Negatively Charged Homotetramer." J. Biol. Chem., Vol. 264, No. 28, pp. 16776-16785. (1989).	
	CQ2**	Lamb et al., "Effects of FK506 and Rapamycin on Excitation-Contraction Coupling in Skeletal Muscle Fibres of the Rat." J Phys. Vol. 494, No.2, pp. 569-576. (1996).	
	CR2**	Lauffenburger et al., "Receptors." Oxford University Press, Chapter 2, pp. 9-12. (1996).	
	CS2**	Laver et al., "Inactivation of Ca <sup>2+</sup> Release Channels (Ryanodine Receptors RyR1 and RyR2) with Rapid Steps in [Ca <sup>2+</sup> ] and Voltage." Biophys J., Vol. 74, pp. 2352-2364. (1998).	
	CT2**	Lehnart et al. "Cardiac Ryanodine Receptor Function and Regulation in Heart Disease." Ann NY Acad Sci., Vol. 1015, pp. 144-159. (2004).	
	CU2**	Lehnart et al. "Defective Ryanodine Receptor Interdomain Interactions May Contribute to Intracellular Ca <sup>2+</sup> Leak: A Novel Therapeutic Target in Heart Failure." Circulation, Vol. 111, No. 25, pp. 3342-3346. (2005).	
	CV2**	Lehnart et al., "Phosphodiesterase 4D Deficiency in the Ryanodine-Receptor Complex Promotes Heart Failure and Arrhythmias." Cell, Vol. 123, No. 1, pp. 25-35. (October 7, 2005).	
	CW2**	Lehnart et al., "Sudden Death in Familial Polymorphic Ventricular Tachycardia Associated with Calcium Release Channel (Ryanodine Receptor) Leak." Circulation, Vol. 109, pp. 3208-3214. (2004).	
	CX2**	Leistad et al. "Atrial Contractile Dysfunction After Short-Term Atrial Fibrillation is Reduced by Verapamil But Increased by BAY K8644." Circulation, Vol. 93, pp. 1747-1754. (1996).	
	CY2**	Levy et al. "Long-Term Trends in the Incidence of the Survival with Heart Failure." N. Engl. J. Med., Vol. 347, No. 18, pp. 1397-1402. (2002).	
	CZ2**	Lisy et al., "New Cardioprotective Agent K201 is Natriuretic and Glomerular Filtration Rate Enhancing." Circulation, Vol. 113, pp. 246-251. (2006).	
	CA3**	Lunde et al., "Contraction and Intracellular Ca <sup>2+</sup> Handling in Isolated Skeletal Muscle of Rats with Congestive Heart Failure." Circ. Res., Vol. 88, pp. 1299-1305. (2001).	
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